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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,066	01/24/2005	Stanley George Bonney	PG4884USw	7458

23347 7590 07/03/2007
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EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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07/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,066	Applicant(s) BONNEY ET AL.	
	Examiner Nihir Patel	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03.29.2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01.24.2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06.30.06; 01.24.05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. In response to applicant's arguments, the recitation "A unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Figures 1 and 2 of the Makiej reference clearly shows that the device is capable of delivering a first medicament and at least one further medicament as a combination medicament product.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims **1-4 and 11-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makiej (US 5,002,048) in view of Weinstein (US 6,382,205).

Makiej discloses a unitary medicament dispenser device comprising a first medicament dispenser (**18**) for the delivery of the first medicament and at least one further medicament dispenser (**20**) for the delivery of the at least one further medicament. The first and the at least one further medicament dispenser enable the first and the at least one further medicament to be kept separate until the point of delivery (**Fig. 1**). Makiej does not disclose that the first medicament dispenser is different in type to the at least one further medicament dispenser.

However, Weinstein '205 teaches two separate medicament dispensers, where the first medicament, dispenser (**1**) is different from the second medicament dispenser (**2**) (**Figure 1**).

Therefore, it would have been obvious, to one having, ordinary skill in the art at the time of the invention, to modify the device of Makiej so that it would have two separate medicament dispensers, where the first medicament dispenser is different in type from at least one further medicament dispenser, as taught by Weinstein '205, as such a modification would allow a user to use a particular dispenser of the device depending on which dispenser is needed for the situation, as appropriate.

5. Claims **5-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makiej (US 5,002,048) in view of Weinstein (US 6,382,205) and further in view of Marand (US 3,704,725).

Makiej/Weinstein do not teach a unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product.

However, Marand teaches a unitary medicament dispenser (**Figure 1**), product container (**first**

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medicament dispenser), (1) and a propellant: cartridge (at least one further medicament dispenser) (9), that dispenses a combination medicament product by means of coupler-aspirator (3). Therefore, it would have been obvious, to one having ordinary skill in the art at the time of the invention, to modify the device of Makiej/Weinstein to allow the dispensing of a combination medicament product, as taught by Marand, as such a modification would allow a user or patient to inhale a specialized medicament for an appropriate treatment that results from two separate initial medicaments.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

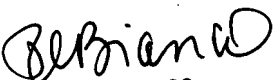
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nihir Patel


PATRICIA BIANCO
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